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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/775,281	02/01/2001	James L. McMenimen	P-9153.01	8273

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EXAMINER

JASMIN, LYNDA C

ART UNIT PAPER NUMBER

3627

DATE MAILED: 10/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

SK

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/775,281	MCMENIMEN ET AL.
	Examiner	Art Unit
	Lynda C Jasmin	3627

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 01 February 2001.

2a) This action is **FINAL**.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-8 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-8 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 25 May 2001 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.

4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Drawings***

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "60" has been used to designate both "outer housing" in Fig. 2 and "information network" in Fig. 3. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### ***Specification***

2. The disclosure is objected to because of the following informalities: on page 16 reference character 60 is referred as "outer housing" and on page 17, line 20 it is referred as "information network" consistency is required.

Appropriate correction is required.

3. Claim 7 is objected to because of the following informalities: at line 8, the term "lest" should be --least--. Appropriate correction is required.

### ***Double Patenting***

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11

Art Unit: 3627

F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-4 and 6-8 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 5-7 of copending Application No. 09/775,262. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the present application with the medical device management method and system of copending application 09/775,262, and achieved the same end result.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-3, 5 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Duffin et al. (5,752,976).

Duffin et al. discloses a medical device management system as claimed having a web-enabled information network (via 50), a programmer (via 20), at least one implanted medical device (12, 14), deployed from a known source (physicians office or clinic). The web-enabled information network (50) is in bi-directional data communications scheme with the programmer (20) (col. 5, lines 31-37). The web-enabled information network (50) implements a global communications and monitoring system (as illustrated in Figure 1).

The web-enabled information network (50) includes one of a satellite based telecommunications link and a cellular link (col. 6 lines 27-35). The at least one implanted medical device (12, 14) includes one of an old implant needing an upgrade (col. 14, lines 24-31). The known source includes at least one of a hospital with data communications with the web-enabled information network (col. 5, lines 38-50).

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 4, 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duffin et al. (5,752,976), in view of Colligan et al. (6,298,443 B1).

Duffin et al. discloses all the elements of the claimed invention, but fails to disclose storing manufacturing information about the implanted medical device, data communication with shipping/delivery, maintaining an inventory, updating the inventory by implementing a build-to-order/build-to-replenish operation, and maintaining device identity via programmer interface.

Colligan et al. discloses the concept of having a build-to-order custom-programmed CD ROM that is configured for a specified individual computer system

(with Service Tag number of the specified computer system) and constraint to be downloaded to and operable on only the specified individual computer system. Colligan et al. also discloses a software transport package manufacturing process (300) to retrieve customer order record by part number and a shipping method. Colligan et al. further discloses the concept of maintaining and inventory via an asset tag (col. 11, lines 24 and 25).

From this teaching of Colligan et al., it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the implanted medical device management system and method Duffin et al. to include the concept of a customized build-to-order software image to a computer system taught by Colligan et al. in order to fit customer's specific needs.

### ***Conclusion***

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Pirelli (5,611,051) discloses method using a central computer and workstation for managing inventory.

Johnson et al. (5,712,989) discloses a method and system for automatically determined which items in a Just-in-Time inventory are likely to require replenishment.

Linberg (6,385,593 B2) discloses a method and system for remote invoicing and inventory control of medical components of an implantable medical device system.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynda C Jasmin whose telephone number is (703) 305-0465. The examiner can normally be reached on Monday- Friday (8:00-5:30) alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Olszewski can be reached on (703) 308-5183. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7687 for regular communications and (703) 305-7687 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1113.



Lynda C Jasmin  
Examiner  
Art Unit 3627

Ij  
October 15, 2002